

indigent and a strong public interest justifies participation, or (2) the person's participation is in the public interest because it can be considered of primary benefit to the general public.

(c) The Commissioner may grant or deny the petition. If the petition is granted, the participant need file only one copy of each submission with the Dockets Management Branch. The Dockets Management Branch will make sufficient additional copies for the administrative record, and serve a copy on each other participant.

§ 12.83 Advisory opinions.

Before or during a hearing, a person may, under § 10.85, request the Commissioner for an advisory opinion on whether any regulation or order under consideration in the proceeding applies to a specific situation.

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 12.35, the director of the center responsible for the matters involved in the hearing shall submit the following to the Dockets Management Branch:

(1) The relevant portions of the administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record.

(2) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. *Files* means the principal files in the center in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information relied upon.

(4) A narrative position statement on the factual issues in the notice of hearing and the type of supporting evidence the director intends to introduce.

(5) A signed statement that, to the director's best knowledge and belief, the submission complies with this section.

(b) Within 60 days of the publication of the notice of hearing or, if no participant will be prejudiced, within another period of time set by the presiding officer, each participant shall submit to the Dockets Management Branch all data and information specified in paragraph (a)(2) through (5) of this section, and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the data and information specified in paragraph (a)(2) of this section, participants shall exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) Submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen.

(d) A participant's failure to comply substantially and in good faith with this section constitutes a waiver of the right to participate further in the hearing; failure of a party to comply constitutes a waiver of the right to a hearing.

(e) Participants may reference each other's submissions. To reduce duplicative submissions, participants are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

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